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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,990	12/31/2003	Mark Birkenbach	B0801.70226US01	2426

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,990	BIRKENBACH ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-43* is/are pending in the application.

4a) Of the above claim(s) *42, 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12-31-03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Currently, claims 27-43 are pending in the application.

2. Applicant's election of Group IV, drawn to antibodies to Epstein Barr virus induced (EBI) polypeptides, and to embodiments wherein the antibody is directed against the protein identified as EBI 1 (SEQ ID NO: 2) in the reply filed on February 11, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 42 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 11, 2005.

Claims 27-41 are under consideration.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on December 31, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Priority

5. The first paragraph of the specification should be amended to show that the parent application 09/929,583 has issued as patent number 6,699,971.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 27 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This claim is directed to antibodies against the EBI 1 protein. However, as currently drafted, the claim includes antibodies that may occur in nature. The claim therefore reads on non-statutory subject matter. It is suggested that the claims be amended to read on - - isolated- - antibodies.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 27, and 35-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Godiska et al., U.S. Patent 5,759,804 (of record in the December 2003 IDS). These claims are directed to antibodies which bind to the protein of SEQ ID NO: 2.

Godiska teaches a protein identified as V31 or SEQ ID NO: 7. Columns7-8. This protein varies from SEQ ID NO: 2 of the present application in the N-terminus (it does not contain the first 20 amino acids of SEQ ID NO: 2) and at the residues corresponding to residues 182,183, and 337 of SEQ ID NO: 2. The reference also teaches antibodies which bind to this protein. See, column 4 (lines 16-39), and columns 23-24 (teaching the raising of antibodies against both an N-terminal region of V31, and against the external extracellular loops of V31, which comprise only the N-terminal, and the residue 337 differences from SEQ ID NO: 2). In view of the high degree of identity between the two sequences, the antibodies raised by Godiska would have also been able to bind SEQ ID NO: 2. The reference therefore anticipates claims 27 and 35.

With respect to claims 36 and 37, the reference implicitly describes the kits of these claims in columns 23-24, where is discloses the Western blot detection of the antibodies. In the performance of this assay, the reference teaches the separate addition to the protein of 1) the antibodies, and 2) a conjugate according to claim 37 (labeled anti-mouse Ig). Thus, the reference teaches separate containers comprising these elements. The claims also refer to the kit as containing instructions. While such instructions are not disclosed in the patent, it is also noted that such instructions have not been deemed sufficient to distinguish between a claimed invention and the prior art. See e.g., In re Ngai, 70 U.S.P.Q. 2d 1862, at 1864 (stating that in order for printed matter to distinguish a claimed invention from the prior art, the printed matter must be functionally interrelated

with the underlying object, and that instructions on a use for the object are not so interrelated).

It is noted that the Godiska patent has a filing date after the earliest priority date of the present application. However, support for antibodies on which the rejection is based in found in application 07/977,452, which does predate the present application, and to which the Godiska patent claims priority as a CIP. The reference therefore anticipates the indicated claims.

10. Claims 27, 35, 36, and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Bayliss et al., (J Gen Virol 56:105-118- of record in the December 2003 IDS). As indicated above, the claims read on an antibody that binds to the protein of SEQ ID NO: 2. This protein is disclosed in the application as having its expression induced by cell infection by the Epstein Barr Virus (EBV). it is additionally noted that the art teaches that this protein comprises a signal sequence at its N-terminal end, thereby indicating that the mature protein would not include this N-terminal sequence. See, Birkenbach et al., J Virol 67: 2209-20, page 2212, Figure 1. A biopolymer calculator indicates that the molecular weight of the protein with the signal sequence is about 43 kDa, and is about 40 kDa without it. See, Biopolymer calculator results, attached. The claims are thus directed to antibodies that bind to an EBV-induced protein with a molecular weight of about 40 kDa.

Bayliss does not teach the protein sequence of SEQ ID NO: 2. However, the reference does teach a number of proteins, the expression of which is induced by EBV infection. See e.g., page 110. Among the identified EBV induced proteins is a protein of

about 40 kDa according to SDS-PAGE. The reference also teaches that these proteins were separated from cellular extracts in part through immunoprecipitation using EBV positive sera which bound to the expressed proteins. See, pages 106-07. Thus, the reference teaches antibodies directed against an EBV-induced protein of about 40 kDa. The reference therefore anticipates the indicated claims.

It is additionally noted that the Birkenbach reference teaches that the protein was found in lymphocyte cells. Abstract. The teachings of Bayliss relate to proteins identified in Raji cells, which are cells known in the art to be cells from Burkitt lymphoma lines, a tumor known to occur primarily in B-cells. See, U.S. Patent 4,654,419 (column 31, lines 38-41), and definition of Burkitt lymphoma, Stedman's Online Medical Dictionary. Thus, the cells from which the 40 kDa protein of Bayliss were identified provide further evidence that the 40 kDa protein is the same as the protein of SEQ ID NO: 2.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 28, 29, 39, 40, and 41are rejected under 35 U.S.C. 103(a) as being unpatentable over Godiska (supra). These claims limit the claimed inventions to specific forms of antibodies, including monoclonal antibodies and single chain antibodies. While Godiska does not appear to have actually disclosed such antibodies, the reference does suggest the use of these alternative antibody forms. Column 4, lines 16-20. From these

teachings, it would therefore have been obvious to those in the art to make such antibody forms for use in the detection or purification of the target protein as suggested by the reference. Those in the art would have been motivated to make such alternative antibody forms due to the discussion of such in the patent as functional equivalents to isolated antibodies.

Further, because the reference teaches the use of monoclonal antibodies, and the use of hybridoma cells was a well-known and established method for the production of such antibodies(see e.g., U.S. Patent 5,663,303, column 9, lines 13-18, and 54-59), the teachings of the reference also implicitly render the hybridoma cells of claims 40 and 41 obvious.

13. Claims 28-35, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Godiska as applied to claims 27, and 35-37 above, and further in view of either of U.S. Patents 5,663,303, or 6,194,561. These claims read on antibodies or antibody fragments that bind to SEQ ID NO: 2, and to embodiments wherein the antibodies are detectably labeled. While the Godiska reference teaches antibodies that bind to SEQ ID NO: 2 (as described above), the reference does not teach binding fragments of the antibodies, or the detectable labeling. However, the reference does teach the use of the antibodies for the purification and detection of the target antigen. Column 4, lines 25-29. The art teaches the use of antibodies, including antibody fragments, and the labeling of such antibodies, in methods for the detection of proteins. See e.g., the teachings of columns 7-8, and 9-10 of U.S. Patent 5,663,303; and column 10 (lines 7-15) and columns 27-28 of U.S. Patent 6,194,561. Because the art teaches that

such labeled antibodies and antibody fragments are useful in methods of detecting a target antigen, and because Godiska teaches the use of the antibodies disclosed therein for the detection of the protein, it would have been obvious to those in the art to use any of such labeled antibodies or antibody fragments for the detection of the protein. Those in the art would have been motivated to use the labeled antibodies because the use of labels allows for easy determination as to the assay results.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 3/7/05

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